



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/DK87/00129 <b>(22) International Filing Date:</b> 19 October 1987 (19.10.87) <b>(31) Priority Application Number:</b> 5014/86 <b>(32) Priority Date:</b> 20 October 1986 (20.10.86) <b>(33) Priority Country:</b> DK  <b>(71) Applicant (for all designated States except US):</b> COLO-PLAST A/S [DK/DK]; Kokkedal Industripark 40, DK-2980 Kokkedal (DK). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only) :</b> MORRIS, Michael [DK/DK]; Lyneborggade 10 st., DK-2300 Copenhagen S (DK).  <b>(74) Agent:</b> INTERNATIONALT PATENT-BUREAU; Nybrogade 12, DK-1203 Copenhagen K (DK).		<b>(81) Designated States:</b> AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent), US.  <b>Published</b> <i>With international search report.</i> <i>In English translation (filed in Danish).</i>
<b>(54) Title:</b> APPLICATOR FOR AN ELASTIC SHEATH-LIKE DISPOSABLE DEVICE, COMBINATION OF AN ELASTIC SHEATH-LIKE DISPOSABLE DEVICE AND APPLICATOR AND A PROCESS FOR MANUFACTURING OF THE COMBINATION  <div data-bbox="431 1234 1252 1619" data-label="Image"> </div> <b>(57) Abstract</b> <p>An elastic sheath-like device (1) in the shape of a contraceptive or urinary condom or a bandaging product is attached to an applicator (3) comprising a proportionately stiff, thin-walled ring-shaped member (8) with a short axial length. A preferably up-rolled part (7) of the sheath-like device (1) is placed in a groove (6), which is shaped with one end of the ring-shaped member (8) between an edge (9) of a ring-shaped external wall (10) and an outwardly turned bead (11) at the upper edge of an internal wall section (12). To press out the part (7) of the sheath-like device (1) placed in the groove (6) serves a part (14) of the external wall (10) between principally axial slots (15, 16) together with a member (17) under the up-rolled part (7) in the groove (6) and a pivoting ejector member (13). The diameter of the ring-shaped member (8) is exactly so much larger than the diameter of the sheath-like device in unextended condition, that a wall section (33) of the sheath-like device (1) is outstretched like a membrane in an essentially normal plane to the ring-shaped member (8) for the purpose of applying an adhesive substance (34) on said wall section (33) after fitting the sheath-like device (1) in the applicator (3). Furthermore the invention concerns a process for manufacturing a combination of the elastic sheath-like device (1) and the applicator (3).</p>		

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Applicator for an elastic sheath-like disposable device, combination of an elastic sheath-like disposable device and applicator and a process for manufacturing the combination.

This invention relates to an applicator to be used for arranging an elastic sheath device on an elongated body, in particular with respect to the arrangement of a contraceptive or urinary condom or a medical bandage article on a body portion, comprising a  
5 comparatively rigid, thin-walled annular member of short axial length and a diameter exceeding the diameter of the sheath unit in a non-expanded state as well as the largest transverse measurement of said body,  
10 said annular member being at its one end adapted to secure part of the sheath unit which is located within the annular member.

Flexible sheath devices of the type referred to are inter alia used as disposable catheters or urinary  
15 condoms in male incontinence equipments, the sheath device being open at one end and having at the other end a spout-shaped outlet adapted to be connected with a urine collection bag expediently fastened to user's legs.

20 In view of the fact that the users are frequently elder and disabled persons, there is as regards the designing of such articles attached great importance to facilitate the handiness as much as possible when arranging the catheter on user's penis and further to minimize the physical and psychical embarrassing problems  
25 involved in case the arranging must be performed by the nursing personnel.

The fastening of a urinary condom to a flaccid penis is generally effected by gluing with a pressure  
30 sensitive adhesive. This may for instance be effected in that an adhesive strip is wound around penis prior to arranging the condom, as known inter alia from GB

patents Nos 1,459,486, 2,099,706 and 2,099,707 and from the published international patent specification No. 64,529. In more recent product designs an attempt has, however, been made to eliminate the necessity of  
5 separately arranging an adhesive member prior to arranging the condom by providing the condom proper with an internal coating of a pressure sensitive adhesive, such as disclosed inter alia in GB patent No. 2,106,784 and published international patent specifica-  
10 tion No. W086/00816, according to which a so-called one-piece product is obtained offering the user a comparatively easy handling.

In order to further facilitate the handiness when arranging the condom, various types of applicators  
15 have been suggested with a view to eliminate the necessity of directly touching the penis.

From GB patent No. 1,595,711 it is known to attach a contraceptive condom of substantially conical shape to one end of an annular applicator made from a  
20 plastic material, rigid paper or cardboard by gluing to the applicator edge an adhesive preferably consisting of gelatin and water allowing the applicator ring to be manually detached once the condom has been arranged.

The disclosure of the published GB patent specification No. 2,107,194 deals with an applicator  
25 designed as a plate of relatively rigid material, preferably a plastic material as for instance hard polyethylene in which a convex opening of larger periphery than the edge portion of the flexible sheath device in  
30 a non-expanded state, the rolled-up edge portion of the sheath device being stretched by means of two projections protruding from the edge of the opening.

According to an embodiment disclosed in the published international patent specification No.  
35 W081/03609 use is made of a funnel-shaped conical applicator encircling the condom whose edge portion at

the open end is bent about the edge of the applicator. Said applicator is supplied together with the condom in a flat state and is expanded to the desired form prior to its being arranged by squeezing together the comparatively sharp edges of the applicator. Said design  
5 of the applicator involves the risk that the comparatively sharp edges may damage the condom proper, particularly when stored for a longer time. The applicator is moreover less fitted for condoms delivered in a  
10 rolled-up or partially rolled-up state.

From the published European patent specification No. 68712 it is known to secure a condom in a rolled-up state within a tubular applicator with grooves at either end, the rolled-up portion of the condom being  
15 secured in the groove at one end of the applicator while the groove at the opposite end serves to fasten a flexible retainer ring that is delivered together with the applicator and condom and serves to fasten the non-adhesive condom after its being arranged, the retainer  
20 ring being placed immediately behind glans penis.

US patent No. 4,540,409 relates to an embodiment in which the outlet or spout end of a fully rolled-off condom is located internally of a conical, tubular applicator, while the remaining portion of the length of  
25 the condom towards the open end is located on the external surface of the applicator and is fastened thereto by an adhesive strip. The opening of the applicator at the end which upon arrangement is being passed over penis is comparatively narrow in comparison with penis  
30 itself, so that said applicator does not to any appreciable extent minimize the troubles of use occurring when arranging a condom without the aid of an applicator.

Finally, US patent No. 4,589,874 deals with an  
35 applicator of the type mentioned in the opening portion and adapted to be used in conjunction with a condom

supplied in a rolled-up state, the rolled-up portion of which being fastened by an external bulb at one end of the axially, comparatively short annular applicator. This applicator too has, however, a comparatively confined clearance relative to penis.

A considerably improved handiness is according to the invention obtained for an applicator of the type mentioned by way of introduction in that a groove provided at said one end of the annular member and adapted to receive said portion of the sheath device is confined by a projecting edge of an annular external wall and an outwardly extending bulb at the upper edge of an oppositely positioned internal wall portion and that the part of the external wall positioned between substantially axially directed slits in connection with the member positioned beneath the portion of the sheath device accommodated in the groove constitutes a pivotally movable ejector member by which the portion of the sheath device inserted in the groove may be pressed out of the groove.

The design of the applicator with said pivotal ejector member, upon whose operation the portion of the sheath device accommodated in the groove, e.g. a rolled-up portion of the sheath device, is automatically pressed out of the groove reduces to a minimum the necessity of touching and manipulating upon arranging the condom, since the rolled-up portion of the condom does not have to be pressed manually over a comparatively wide bulb - as is the case with the last mentioned known design - so that the only manual operation requiring to touch the condom proper is to roll off a possibly rolled-up portion of the condom.

The applicator may be used with rolled-up as well as unrolled condoms, the latter being for instance designed so that they cover merely part of the length of penis as known per se. The applicator may further

have a considerably larger clearance compared to the body on which the sheath device is to be arranged than is the case with more of the above mentioned prior applicator designs.

5           Due to the fact that the applicator is determined to be delivered together with a disposable contraceptive or urinary condom or a bandaging article, the invention further relates to the combination of a flexible sheath-like disposable device to be used as a  
10   contraceptive condom, urinary condom or bandaging article, including an applicator to be used for the arrangement of the article on a body portion, said disposable article comprising an elastic sheath device, part of which from an open end is detachably secured to  
15   the applicator at one end of a comparatively rigid, thin-walled annular member of short axial length and a diameter exceeding the diameter of the sheath device when non-expanded as well as the largest transverse measurement of said body portion.

20           According to the invention said combination is characterized in that said part of the sheath device is secured in a groove at said end of the annular member and that the portion of the sheath device located within the annular member includes a wall section which  
25   is expanded like a diaphragm within said groove substantially in a normal plane relative to the axis of the annular member, a pivotally movable ejector member positioned between substantially axially oriented slits in the annular member comprising a member positioned  
30   beneath the portion of the sheath device accommodated in the groove.

          The form of said wall section expanded like a membrane between the rolled-up part of the sheath device accommodated in the groove and its free, preferably  
35   ably closed end which in a urinary condom is provided with an outlet spout provides for obtaining a very simple and safe arrangement.

In a preferred embodiment particularly fitted for urinary condoms the sheath device on said expanded wall section may have a pressure sensitive adhesive coating covered by a detachable covering layer with an adhesive releasing coating. Just by making use of the wall section expanded substantially in a radial plane to the adhesive coating, a considerable simplification with a view to production is obtained by applying the adhesive to the interior of a sheath-like device of the present type, the adhesive being applied after the sheath device, mainly made from latex, has been mounted on the applicator so that the applying of adhesive is effected on a substantially plane surface, e.g. by means of a roller, a brush or the like.

This provides for obtaining the particular advantage of the adhesive coating that the adhesive in the supply state is not confined between the windings of the rolled-up part of the sheath device. This opens up various possibilities of choosing an adhesive, for instance an adhesive that is inapt with respect to the above mentioned prior designs of so-called "one-piece" articles because they include components unfitted for contact for a longer time with the latex material of the sheath device in the rolled-up state.

The invention makes it possible to use an adhesive with the utmost properties with respect to resiliency, sealing ability and handiness, e.g. a stomic adhesive of a type per se known from the accepted Danish patent application No. 147,034, in that it must be assured that the coating does not get in contact with the latex material by inserting a barrier layer, made e.g. from a thermoplastic sheet, between the expanded wall section and the adhesive coating.

A preferred embodiment of the above combination is therefore characterized in that the adhesive coating is applied to a barrier layer placed on said wall sec-



tion and comprises a stomic adhesive of the type including a gel-like, at least weak resilient mixture composed of a physical cross linked elastomer, one or more hydrocarbon-gel-adhesive resins selected from polymers and copolymers of dicyclopentadien,  $\alpha$ -pinen and  $\beta$ -pinen together with an oil-extender and optionally an antioxidant and a discontinuous phase containing one or more hydrocolloides.

It has turned out, moreover, that such a stomic adhesive is easy to apply and does not cause the formation of furrows when the resilient sheath-like device after having left the applicator assumes its circular-cylindrical form.

The invention further relates to a method of producing a combination of a flexible sheath-like disposable device to be used as a contraceptive condom, urinary condom or a bandaging article with an applicator to be used for arranging the article on a body portion, said disposable article comprising a flexible sheath device provided with an internal adhesive coating, part of said device being releasably secured from an open end to the applicator at one end of a comparatively rigid, thin-walled annular member of short axial length and a diameter exceeding the diameter of the sheath device in non-expanded state as well as the largest transverse measurement of said body portion.

According to the invention said method provides for obtaining a substantially simplified application of adhesive in that the resilient sheath device when expanded is mounted on a mandrel which at a distance from its free end, corresponding to the desired length of the portion of the sheath device located within the applicator is provided with a shoulder as abutment for the applicator which is then mounted on the mandrel round the sheath device, abutting against said shoulder with its one end that accommodates a groove adapted to

receive and secure the portion of the sheath device located on the other side of the shoulder, following which the applicator including the secured sheath device is removed from the mandrel, thereby expanding  
5 like a diaphragm a wall section of the sheath device substantially in a normal plane to the axis of the annular member of the applicator, whereupon said wall section is provided with a pressure sensitive adhesive coating onto which a releasable covering layer is ap-  
10 plied.

In accordance with the above mentioned preferred embodiment of the combination of the applicator and disposable article a preferred embodiment of the method is characterized in using a pressure sensitive coating  
15 as a stomic adhesive of the type comprising a gel-like, at least weak resilient mixture composed of a continuous phase containing a physical cross linked elastomer, one or more hydrocarbon-gel adhesive resins selected among polymers and copolymers of dicyclopentadien,  
20  $\alpha$ -pinen and  $\beta$ -pinen together with an oil-extender, and optionally an antioxidant and a discontinuous phase containing one or more hydrocolloids, and in that said adhesive is applied as a barrier layer placed beforehand on the expanded wall section.

25 In the following the invention will be further explained with reference to the drawings, in which

Fig. 1 illustrates an embodiment of a combination of a urinary condom and an applicator according to the invention,

30 Fig. 2 is a perspective view of an embodiment of the applicator proper,

Fig. 3 an enlarged sectional view of the applicator in Fig. 2,

35 Fig. 4 is a view of the ejector member of the applicator,

Fig. 5 is a sectional view of a second embodiment,

Figs 6 to 10 illustrate the use of the applicator, and

Figs 11 and 12 illustrate a method of producing an applicator-condom combination as illustrated in Figs 1 to 3.

Fig. 1 is a perspective view of an embodiment of a disposable article in the form of a combination according to the invention of a resilient sheath device formed as a urinary condom 1 with an outlet spout 2 and an applicator 3, the detailed construction of which will be described in the following. Fig. 1a shows condom 1 with applicator 3 in the supply state in which the open end is covered by a releasable cover paper 4 with a tear-off flap 5. Fig. 1b illustrates the condom-applicator combination relieved of cover paper 4.

As explained in detail in the following a groove 6 is formed at the open end of the applicator, said groove being adapted to retain a rolled-up portion 7 of condom 1 on part of its length from the open end.

As illustrated in Figs 2 and 3 the applicator proper includes a comparatively rigid, thin-walled annular member 8 of short axial length and a diameter which in order to obtain an easy and handy arrangement of condom 1 exceeds the diameter of the condom in non-expanded state. Groove 6 is at one end of the annular member 8 confined by a projecting edge 9 of an annular outer wall 10 of annular member 8 and an outwardly extending bulb 11 at the top edge of an inner wall section 12 opposite the projecting edge 9. According to the invention applicator 3 is provided with a pivotally movable ejector member 13 formed by a part 14 of outer wall 10 located between substantially axially oriented slits 15, 16 in connection with a member 17 positioned beneath the rolled-up portion 7 of condom 1 accommodated in the groove.

In the illustrated embodiment member 17 is con-

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stituted by part of a bottom section 18 which outside ejector member 13 is formed integrally with outer wall 10 and inner wall section 12. Beyond slits 15 and 16 extending in outer wall 10 the ejector member 13 is  
5 confined by transverse slits 19 and 20 in bottom section 18 and a slit 21 extending in the circumferential direction of annular member 8 between member 17 of the bottom section and inner wall section 12. Ejector member 13 is thus only connected with the part of annular  
10 member 8 located outside slits 15 to 16, 19 to 21 through hinge pin forming joints 22 at the projecting edge 9 of outer wall 10.

The hinge pin forming joints 22 are positioned at a level substantially centrally between bottom section 18 and the outwardly projecting bulb 11 at the up-  
15 per edge of inner wall section 12.

As it will most clearly appear from Fig. 4 it may be advantageous if slit 21 between bottom section 18 and inner wall section 12 extends past slits 15 and  
20 16 in the outer wall, the transverse slits 19 and 20 of the bottom section thereby forming angles of  $45^\circ$  with radii of the annular member 8.

In a schematical sectional view Fig. 5 illustrates a second embodiment in which the substantially  
25 radially oriented slits 23 extend through the entire outer wall 24 and its projecting edge 25, and the portion 26 of the outer wall located between the slits is hingedly connected with a bottom section 27 rigidly united with the inner wall section 28 and the portion  
30 29 of outer wall 24 located outside slits 23. The projecting edge of portion 26 of outer wall 24 located above bottom section 27 will thus constitute the member corresponding to bottom section portion 18 in Fig. 3 and located beneath the part 31 accommodated in groove  
35 30 of said flexible sheath device, e.g. a urinary condom.

As it will most clearly appear from Fig. 3 it is a characteristic feature of the condom-applicator construction according to the invention that the unrolled portion of the condom that is located within annular member 8 includes a wall section 33 expanded like a diaphragm within groove 6 substantially in a normal plane to the axis of the annular member 8. Wall section 33 may suitably be provided with a pressure sensitive adhesive coating 34 which in its state of supply is covered by the releasable cover paper 4.

As it appears from the above, a particular advantage is as well obtained, i.e. in its state of supply the adhesive coating does not occur between the windings of the rolled-up part of the sheath device, contrary to what is the case in prior structures of so-called "one-piece" articles. The choice is then not restricted to an adhesive necessarily capable of standing contact for a longer time with the latex material of the sheath device with a view to storing in the rolled-up state, but it will be possible to choose an adhesive that is optimum as regards leakproof seal and handiness.

As a preferred adhesive use is made of a stomic adhesive of the type known per se from the accepted DK patent application No. 147,034 and including a gel-like, at least weak resilient mixture composed of a continuous phase containing a physical cross linked elastomer, one or more hydrocarbon-gel adhesive resins selected among polymers and copolymers of dicyclopentadien,  $\alpha$ -pinen and  $\beta$ -pinen together with an oil-extender and optionally an antioxidant and a discontinuous phase containing one or more hydrocolloids.

Due to the presence of the oil-extender such an adhesive is unsuitable for contact with latex for a longer period, the oil-extender having a tendency to migrate to the latex material. By applying the adhesive

34a, as schematically illustrated in Fig. 3 on a larger scale, on to a barrier layer 34b, e.g. a thin thermoplastic sheet consisting of nylon, polyethylene, polypropylene, polyurethane and other suitable materials, and  
5 securing it to said wall section by means of a pressure sensitive adhesive 34c fitted for contact with the latex material for a longer time, an adhesive of the recited type which has proven to possess outstanding properties with respect to resiliency, sealing ability  
10 and which is gentle to the skin will be extremely suitable for use in a disposable article combined with an applicator according to the invention.

Said stomic adhesive has further proven to entail the particular advantage that the tendency to form  
15 furrows when said expanded wall section after having left the applicator is made to occupy a substantially circular-cylindrical form.

In order to easier tearing off the cover paper 4 this is preferably annular and has radially oriented  
20 slits 35, as illustrated in Fig. 1a, extending from the inner periphery. Cover paper 4 is applied after condom 1 has been rolled up and positioned within applicator 3 in such a manner that the tear-off flap 5, on the one side of which cover paper 4 further has a radially inwardly extending slit 36 from the outer periphery, is  
25 placed opposite ejector member 13 in order to mark the spot of the annular member of the applicator to be pressed on by user with a view to push the rolled-up part 7 of condom 1 out of groove 6.

30 The releasing action of ejector member 13 is effected by an inwardly directed pressure, e.g. to the position of the outer wall section 14 illustrated in dotted lines in Fig. 3, thereby concurrently pivoting bottom section 18 to a position in which the rolled-up  
35 part 7 of condom 1 is pressed out of groove 6 opposite ejector member 13, the rolled-up part of condom 1 being

thereby completely relieved of applicator 3 by virtue of its elasticity in expanded state.

Figs 6 to 10 illustrate the arrangement of condom 1 by means of applicator 3. Without removing cover paper 4 the condom-applicator combination is being  
5 passed over user's penis until the unrolled part of condom 1 in applicator 3 is filled up throughout its length as illustrated in Fig. 7. In this condition cover paper 4 is torn off by means of tear-off flap 5  
10 and the radial slits 35, 36. By a subsequent pressure on the ejector member 13 condom 1 will get clear of the applicator by a quick snatching movement. The rolled-up part 7 of condom may then be easily rolled on to the remainder of the length of penis, following which condom 1 is affixed by a squeezing motion to activate the  
15 pressure sensitive adhesive.

As it appears from Figs 11 and 12 a condom-applicator combination as dealt with in the preceding may appropriately be performed in that a sheath device 37  
20 made for instance from latex by methods known per se is placed on a mandrel 38 when expanded, said mandrel being provided with a shoulder 39 as abutment for applicator 40 at a distance from its free end corresponding to the desired length of the part of sheath device 37  
25 that is to be accommodated within applicator 39. The applicator 40 is disposed on mandrel 38 round sheath device 37 and abuts against shoulder 39 at the end which has a groove adapted to accommodate and secure the part of sheath device 37 located above shoulder  
30 39.

In the illustrated embodiment the part shown in dotted lines is rolled up in the direction towards applicator and then disposed in its groove. Applicator 40 with the affixed sheath device 37 is subsequently removed from mandrel 38, thereby causing a wall section of  
35 the sheath device to be expanded like a diaphragm sub-

stantially in a normal plane to the axis of the applicator as specified in the above.

As illustrated in Fig. 12, applicator 40 with the affixed sheath device 37 may for instance then be placed on a short supporting tube 41 being a constituent of an automatically applying adhesive equipment not shown. Due to the radially diaphragm-like expansion of the above mentioned wall section a substantially plane surface is obtained for the application of adhesive that may thus be effected in a simple manner by means of a roller, a brush or the like, not shown.

The applicator according to the invention is not restricted to be used in conjunction with urinary condoms of the design illustrated in the drawings in which the condom is supplied when rolled up on part of its length, but the applicator may as well be used in conjunction with short urinary condoms of the type covering only part of the length of penis, the ejector member being easily adapted to grasp at the back of a condom rim fitting comparatively tightly to the outwardly extending bulb at the upper edge of the internal wall section of the applicator annular member.

The applicator is not either restricted to be used in conjunction with urinary condoms for incontinence equipments but it may generally be used as a suitable equipment with respect to any arrangement of an elastic sheath device on an elongated body. As typical examples of other applications may be mentioned contraceptive condoms and various forms of medical dressings and bandage articles made from a plastic material or resilient net materials for the arrangement of fingers, arms or legs.

Nor is the applicator restricted to the illustrated, substantially circular-cylindrical shape of the annular member which may for instance as well be oval or polygonal.



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## P A T E N T C L A I M S

1. An applicator to be used for arranging an elastic sheath device on an elongated body, in particular with respect to the arrangement of a contraceptive or urinary condom or a medical bandage article on a body portion, comprising a comparatively rigid, thin-walled annular member (8) of short axial length and a diameter exceeding the diameter of the sheath unit (1) in a non-expanded state as well as the largest transverse measurement of said body, said annular member (8) being at its one end adapted to secure part (7) of the sheath unit (1) which is located within the annular member (8), characterized in that a groove (6) provided at said one end of the annular member (8) and adapted to receive said portion (7) of the sheath device is confined by a projecting edge (9) of an annular external wall (10) and an outwardly extending bulb (11) at the upper edge of an oppositely positioned internal wall portion (12) and that the part (14) of the external wall (10) positioned between substantially axially directed slits (15, 16) in connection with the member (17) positioned beneath the portion (7) of the sheath device (1) accommodated in the groove (6) constitutes a pivotally movable ejector member (13) by which the portion (7) of the sheath device (1) inserted in the groove (6) may be pressed out of the groove.

2. An applicator as claimed in claim 1, characterized in that the member (17) positioned beneath the part (7) of the sheath device (1) accommodated in groove (6) comprises part of a bottom section (18) which outside ejector member (13) is formed integrally with the outer wall (10) and inner wall section (12) and that beyond said slits (15, 16) in the outer wall the ejector member (13) is confined by transverse slits (19, 20) at the ends of said member (17) of the bottom section (18) and a slit (21) extending in the circum-

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ferential direction of the annular member (8) between said member (17) of the bottom section (18) and the inner wall section (12), the ejector member (13) being only connected with the part of annular member (8) located outside slits (15, 16) through hinge pin forming joints (22) at the projecting edge (9) of the outer wall (10).

3. An applicator as claimed in claim 2, characterized in that the projecting edge (9) of the outer wall (10) with said hinge pin forming joints (22) are positioned at a level substantially centrally between said bottom section (18) and the outwardly projecting bulb (11) at the upper edge of inner wall section (12).

4. An applicator as claimed in claims 2 or 3, characterized in that the slit (21) between the bottom section (17) and the inner wall section (12) is extended past slits (15, 16) in the outer wall and that the transverse slits (19, 20) of the bottom section (18) form angles of 45° with radii of the annular member (8).

5. An applicator as claimed in claim 1, characterized in that the axially oriented slits (23) extend through the entire outer wall (24) and its projecting edge (25) and that the portion (26) of the outer wall (24) located between the slits (23) is hingedly connected with a bottom section (27) rigidly united with the inner wall section (28) and the portion of the outer wall (24) located outside slits (23), the projecting edge above said bottom section of portion (26) of the outer wall (24) located between the slits (23) forming the member located beneath the part (31) accommodated in groove (30) of the sheath device.

6. A combination of a flexible sheath-like disposable device to be used as a contraceptive condom, urinary condom or bandaging article, including an applicator to be used when arranging the article on a bo-

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dy portion, said disposable article comprising an elastic sheath device (1), a part (7) of which from an open end is detachably secured to the applicator (3) at one end of a comparatively rigid, thin-walled annular member (8) of short axial length and a diameter exceeding the diameter of the sheath device when non-expanded as well as the largest transverse measurement of said body portion, characterized in that said part (7) of the sheath device (1) is secured in a groove (6) at said end of the annular member (8) and that the portion of the sheath device (1) located within the annular member (8) includes a wall section (33) which is expanded like a diaphragm within said groove (6) substantially in a normal plane relative to the axis of the annular member (8), a pivotally movable ejector member (13) positioned between substantially axially oriented slits (15, 16) in the annular member (8) comprising a member (17) positioned beneath the portion (7) of the sheath device (1) accommodated in groove (6).

7. A combination as claimed in claim 6, characterized in that the sheath device (1) on said expanded wall section (33) has a pressure sensitive adhesive coating (34) covered by a detachable covering layer (4) with an adhesive releasing coating.

8. A combination as claimed in claim 7, characterized in that the adhesive coating (34) is applied to a barrier layer placed on the bottom wall section (33) and comprises a stomic adhesive of the type including a gel-like, at least weak resilient mixture composed of a physical cross linked elastomer, one or more hydrocarbon-gel-adhesive resins selected from polymers and copolymers of dicyclopentadien,  $\alpha$ -pinen and  $\beta$ -pinen together with an oil-extender and optionally an anti-oxidant and a discontinuous phase containing one or more hydrocolloides.

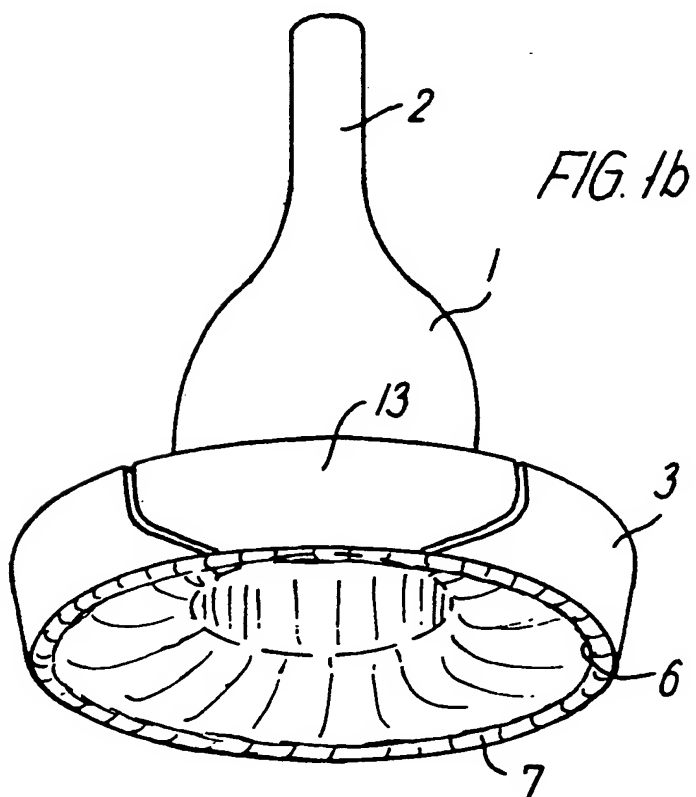
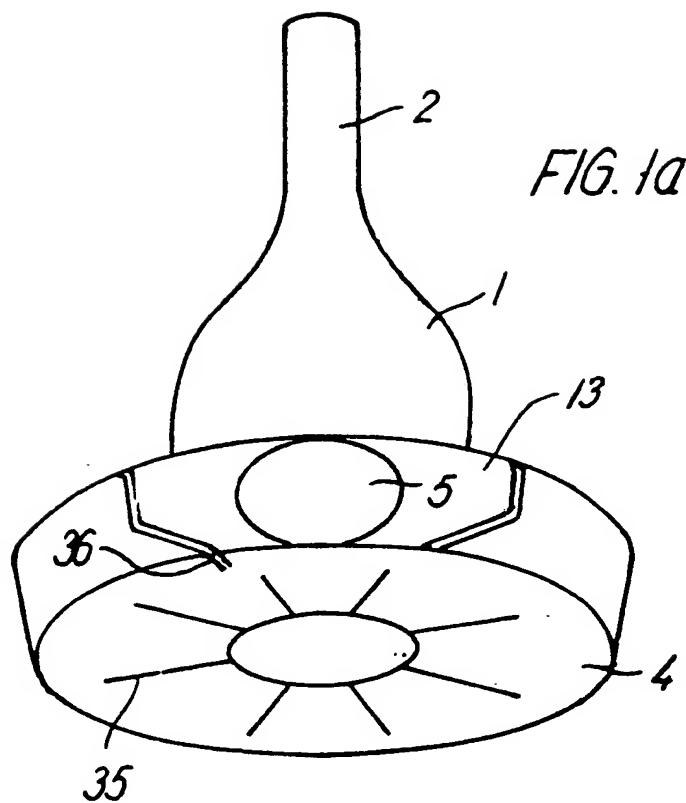
9. A combination as claimed in claim 7 or 8, characterized in that the covering layer (4) is annular and is provided with radially directed slits (35, 36) extending from the internal periphery.

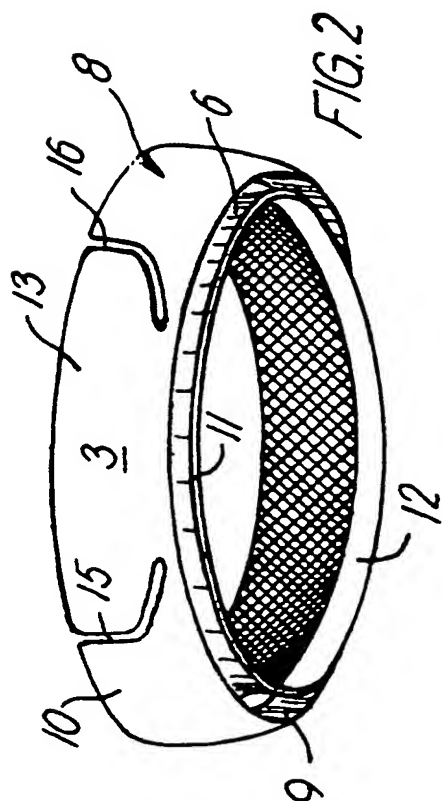
5 10. A combination as claimed in claim 7, 8 or 9, characterized in that the covering layer (4) is provided with a marking and tear-off flap (5) located opposite ejector member 13.

10 11. A method of performing a combination of a flexible sheath-like disposable device to be used as a contraceptive condom, urinary condom or a bandaging article with an applicator to be used for arranging the article on a body portion, said disposable article comprising a flexible sheath device (1) provided with an  
15 internal adhesive coating and of which a part (7) from an open end is releasably secured to the applicator (3) at one end of a comparatively rigid, thin-walled annular member (8) of short axial length and a diameter exceeding the diameter of the sheath device in non-  
20 expanded state as well as the largest transverse measurement of said body portion, characterized in that the resilient sheath device (37) in expanded state is mounted on a mandrel (38) which at a distance from its free end, corresponding to the desired length of the  
25 portion of the sheath device located within the applicator is provided with a shoulder (39) as abutment for the applicator (40) which is then mounted on the mandrel (38) round the sheath device (37), abutting against said shoulder (39) with its one end that accom-  
30 modates a groove adapted to receive and secure the portion of the sheath device (37) located on the other side of the shoulder (39), following which the applicator (40) including the secured sheath device (37) is removed from the mandrel (38), thereby expanding like a  
35 diaphragm a wall section of the sheath device substantially in a normal plane to the axis of the annular

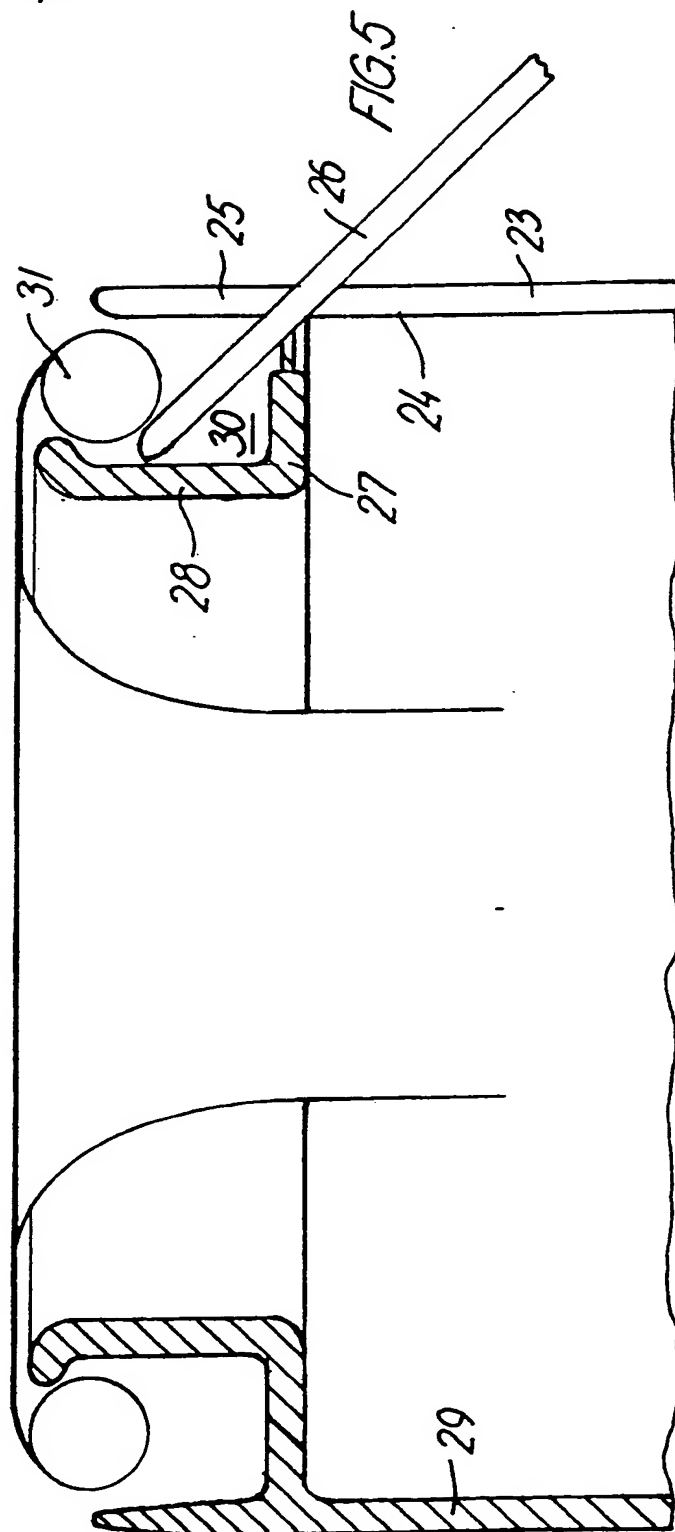
member of the applicator, whereupon said wall section is provided with a pressure sensitive adhesive coating onto which a releasable covering layer is applied.

12. A method as claimed in claim 11, character-  
5 ized in using a pressure sensitive coating as a stomic adhesive of the type comprising a gel-like, at least weak resilient mixture composed of a continuous phase containing a physical cross linked elastomer, one or more hydrocarbon-gel adhesive resins selected among po-  
10 lyomers and copolymers of dicyclopentadien,  $\alpha$ -pinen and  $\beta$ -pinen together with an oil-extender, and optionally an antioxidant and a discontinuous phase containing one or more hydrocolloids, and in that said adhesive is ap-  
plied on a barrier layer placed beforehand on the ex-  
15 ,panded wall section.





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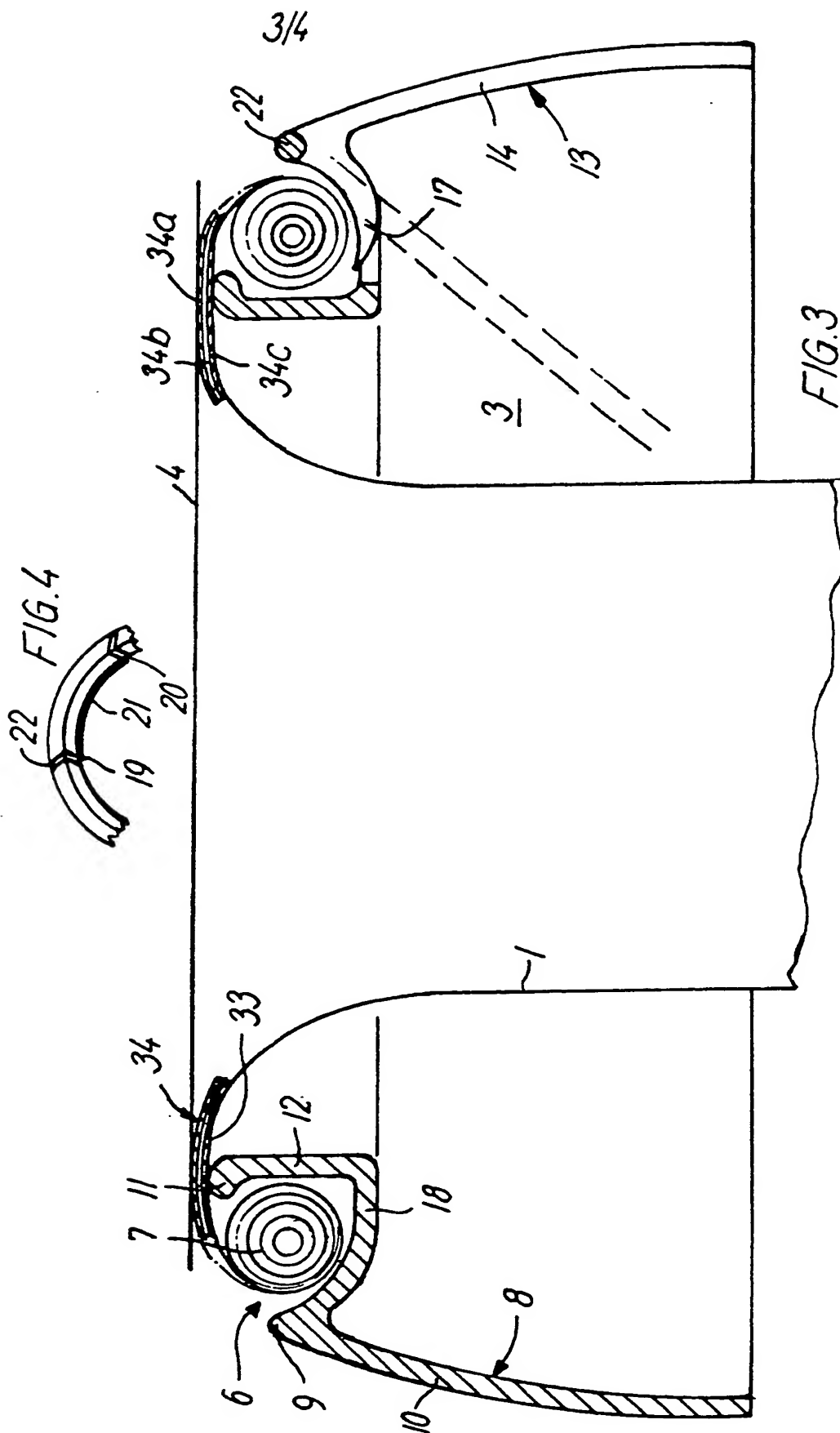




FIG. 6

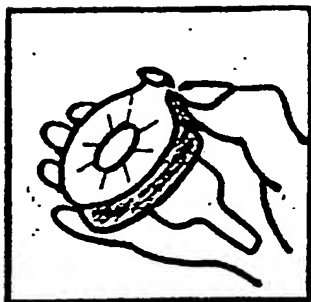


FIG. 7

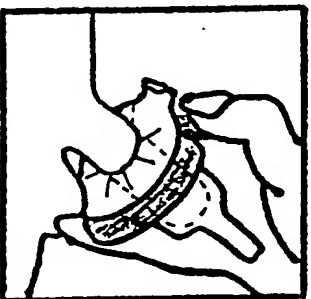


FIG. 8



FIG. 9

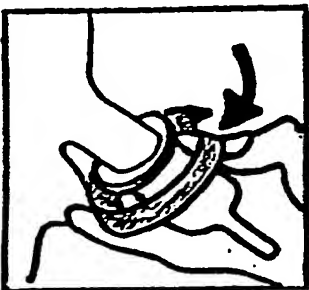
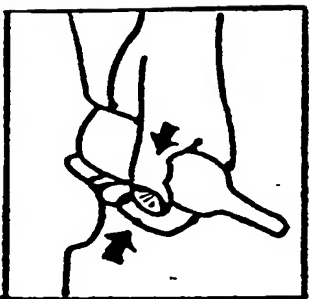


FIG. 10



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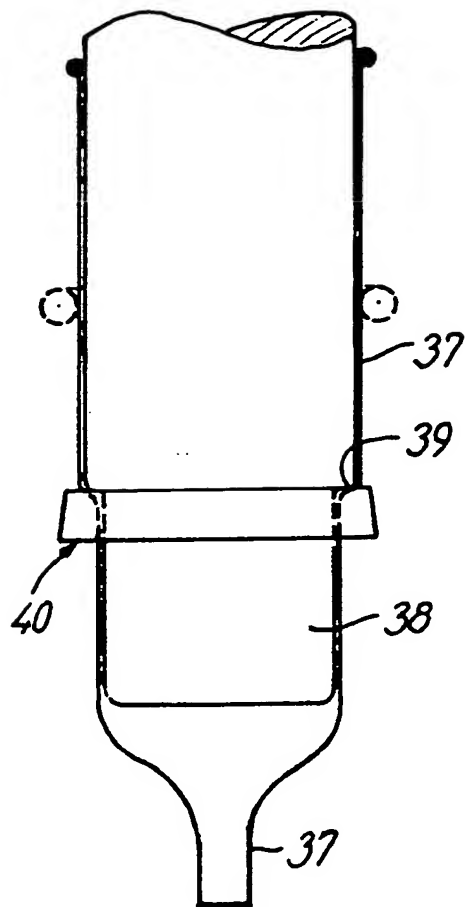


FIG. 11

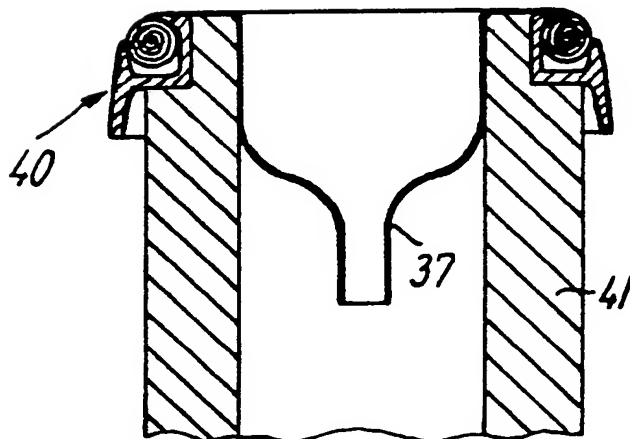


FIG. 12

# INTERNATIONAL SEARCH REPORT

International Application No PCT/DK87/00129

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC <sup>4</sup> A 61 F 5/453		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
IPC 4 US C1	A 61 F 5/40, /44, /453 <u>128</u> : 295; <u>604</u> : 349-353	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>8</sup>		
SE, NO, DK, FI classes as above		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>		
Category <sup>9</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
A	GB, A, 2 107 194 (COLOPLAST A/S) 27 April 1983	
A	EP, A1, 0 068 712 (E R SQUIBB & SONS, INC) 5 January 1983	
A	WO, A1, 81/03609 (LENNART INGVAR BRENDLING) 24 December 1981	
A	US, A, 4 540 409 (NYSTRÖM ET AL) 10 September 1985	
A	US, A, 4 589 874 (RIEDEL ET AL) 20 May 1986	
A	US, A, 2 789 560 (P WEIMAR) 23 April 1957	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
1988-01-20	1988 -02- 02	
International Searching Authority	Signature of Authorized Officer	
Swedish Patent Office	Johan Löfstedt	

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE <sup>1</sup>

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ..... because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claim numbers ..... because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claim numbers ..... because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING <sup>2</sup>

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-5: Product...

Claims 6-10: Combination...

Claims 11-12: Process for manufacturing...

This may be in conflict with some national laws.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
  
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
  
4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.